DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/560,226 filed on December 12, 2005 and is a first action based on the merits of the application. The amended specification and claims document(s) filed on December 12, 2005 is/are being considered by the examiner.

Specification

1. The disclosure is objected to because of the following informalities: On page 1 of the application Roche Diagnostics is listed as the applicant. In this application the applicants are the inventors listed in the Oath and Declaration not Roche Diagnostics. Appropriate action is required.

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. **Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading** (emphasis added). If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification lacks a heading for a majority of the above sections (a)-(l). The headings should appear in uppercase, without underlining or bold type above their respective sections. Appropriate action is required.

Claim Objections

3. Claim 26 is objected to because of the following informalities: Claim 26 states the structure "a lancet tip protective element" which was stated in claim 18. "a" should be replaced with "the." Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 recites the limitation "the puncturing position" in claim 18. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9, 13, 18, 19, 20, 22-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Fritz et al. (US 2002/0120216 A1).

Regarding claim 1 Fritz discloses a blood withdrawal system for collecting blood for analytical or diagnostic purposes, comprising:

a housing (housing 11, see Figure 2b) with an exit opening for the lancet tip of the lancet needle of a lancet (lancet 1, see Figures 2a and 2b) that is moved in the housing along a predetermined puncturing path (opening 13, see Figure 2a),

a lancet guide (moveable part 15 has a semicircular recess which partially encloses the lancet) which guides the lancet along the predetermined puncturing path,

a lancet drive (drive device comprising a drive element 6 a retraction device 7 and a transport device 18, see Figure 3 and [0067]) which drives the lancet moved along the predetermined puncturing path in the puncturing direction until its tip is in a puncturing position (puncturing position is shown in Figure 2a), a lancet storage container (a storage area, see Paragraph [0035]) arranged in the housing and in which a plurality of lancets is stored at a removal position for removal from the lancet storage

container (a plurality of lancets are stored in a removal position for removal after use see Figures 2a and 2b),

a lancet tip protective element (the lancet has a protective element the lancet body 3, see Figures 4a and 4b), into which the lancet tip can be inserted before or after a puncturing motion, whereby the protective element mechanically and hygienically protects a lancet tip that is inserted therein (the lancet body top may be sealed with a elastic material, see [0069]), and the lancet tip protective element arranged on the lancet tip in a parking position of the lancets the parking position not coinciding with the removal position or the puncturing position (Figure 2a shows the lancet tip having several positions including a parking position which does not coincide with the removal and puncturing positions).

Regarding claim 2 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element and the parking position are arranged proximate the exit opening (Figures 2a and 2b show the parking position and protective element are proximate the opening 13).

Regarding claim 3 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element is stationary in the housing, (Figure 2a, shows the protective element is stationary in the housing while the needle is in the puncture position).

Regarding claim 4 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element is adapted to be driven onto the lancet tip (the protective element comprises a soft, deformable elastic material which can be pierced by the tip of the lancet needle without damaging the tip, see [0021])

Regarding claim 5 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet can be driven by the lancet drive (the drive device [0067]) into the parking position, in which the lancet tip is situated in the lancet tip protective element (see Figure 3).

Regarding claim 6 Fritz discloses the blood withdrawal system of claim 1 as set forth above, further comprising a holding facility (moveable part of retraction device 15, see Figure 3 (note 15 has been mislabeled as the spring 16, but the spring 16 is clearly shown in the figure with the proper identifier)) for holding the lancet in the parking position.

Regarding claim 7 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element is arranged such that the lancet tip can be inserted into the lancet tip protective element by a motion that proceeds parallel to the puncturing motion (during the return motion the lancet tip is inserted into the elastic material by a motion that proceeds parallel to the puncturing motion, see [0021] and Figure 2a).

Regarding claim 8 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element is arranged in the lancet storage container (Figure 2 shows the protective element is arranged on the lancet in the lancet storage container).

Regarding claim 9 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element comprises an elastic material (the lancet body is made of an elastic material, see [0021]) into which the lancet tip can be inserted.

Regarding claim 13 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein the lancet tip protective element is replaceable (Figures 2a and 2b show a system wherein the lancets and the lancet tip protective elements are replaceable).

Regarding claim 18 Fritz discloses a method for drawing a blood sample with a blood withdrawal system for collecting blood for analytical or diagnostic purposes, comprising:

a housing (housing 11, see Figure 2b) with an exit opening (opening 13, see Figure 2a), for the lancet tip of the lancet needle of a lancet (lancet 1, see Figures 2a and 2b) that is moved in the housing along a predetermined puncturing path (see Figure 2a) and,

a lancet guide (moveable part 15 has a semicircular recess which partially encloses the lancet) which guides the lancet along the predetermined puncturing path and,

a lancet drive (drive device comprising a drive element 6 a retraction device 7 and a transport device 18, see Figure 3 and [0067]) which drives the lancet in the puncturing direction, a lancet storage container arranged in the (the system can also have separate storage areas for unused and used lancets, see Paragraph [0035]) housing and in which a plurality of lancets store stored at a removal position for removal from the lancet storage container (a plurality of lancets are stored for removal after use see Figures 2a and 2b),

the method comprising , inserting the lancet tip into a lancet tip protective element (the lancet has a protective element the lancet body 3, see Figures 4a and 4b) before or after a puncturing motion, whereby the protective element mechanically and hygienically protects a lancet tip that is inserted therein (the lancet body top may be sealed with a elastic material, see [0069]), and arranging the lancet tip protective element on the lancet tip in a parking position of the lancets, whereby the parking position does not coincide with the removal position and the puncturing position (Figure 2a shows the lancet tip having several positions including a parking position which does not coincide with the removal and puncturing positions).

Regarding claim 19 Fritz discloses method of claim 18 as set forth above, wherein the lancet tip protective element and the parking position are arranged

proximate the exit opening (Figures 2a and 2b show the parking position and protective element are proximate the opening 13).

Regarding claim 20 Fritz discloses method of claim 18 as set forth above, wherein the lancet tip protective element is stationary in the housing, (Figure 2a, shows the protective element is stationary in the housing while the needle is in the puncture position).

Regarding claim 22 Fritz discloses method of claim 18, further comprising driving the lancet into the parking position (the lancet is driven into the parking position by the transport device, see [0067]), in which the lancet tip is situated in the lancet tip protective element (see Figures 2a and 3).

Regarding claim 23 Fritz discloses method of claim 18, further comprising holding the lancet in the parking position by a holding facility (moveable part of retraction device 15, see Figure 3 (note 15 has been mislabeled as the spring 16, but the spring 16 is clearly shown in the figure with the proper identifier)).

Regarding claim 24 Fritz discloses the method of claim 18 as set forth above further comprising arranging the lancet tip protective element such that the lancet tip is inserted into the lancet tip protective element by a motion that proceeds parallel to the puncturing motion (during the return motion the lancet tip is inserted into the elastic

material by a motion that proceeds parallel to the puncturing motion, see [0021] and Figure 2a).

Regarding claim 25 Fritz discloses method of claim 18, further comprising transporting a lancet that was used to perform a puncturing motion is to the lancet storage container (the system can have separate storage areas for used and unused lancets, and is transported using the transport device 18, see Figure 3 and [0035]).

Regarding claim 27 Fritz discloses method of claim 18 further comprising replacing the lancet storage container, (the magazine can be removed and replace with a new magazine, see [0040]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 10, 11, 14, 15 and 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fritz in view of Heller et al. (US 2001/0041904).

Regarding claim 10, Fritz discloses the blood system of claim 1 as set forth above characterized in that the lancet tip protective element is made of an elastic material, see [0021]. Fritz fails to disclose the system wherein the protective element comprises a sterilizing, microbicidal, inactivating, disinfecting, bacterialcidal or fungicidal material for cleaning or protecting the lancet tip. Heller teaches a lancet device comprising (see Abstract) a lancet tip (lancet 102 in Figures 6 and 7 has a tip) with a protective element (sleeve 104) comprising a sterilizing, microbicidal, inactivating,

disinfecting, bacterialcidal or fungicidal material for cleaning or protecting the lancet tip (see Heller [0041] and [0042]).

Both Fritz and Heller teach lancet devices it would have been obvious to a person of ordinary skill at the time of the invention to modify protective element in the system taught by Fritz by incorporating the materials taught by Heller in order to prevent the contamination of the lancet tips since many diabetic people use lancet tips multiple times to lower the cost of monitor their glycemia, see Heller [0003].

Regarding claim 11, Fritz discloses the blood system of claim 9 as set forth above. Fritz fails to disclose the device wherein the elastic material comprises a sterilizing, microbicidal, inactivating, disinfecting, bacterialcidal or fungicidal material for cleaning or protecting the lancet tip. Heller teaches a lancet device comprising (see Abstract) a lancet tip (lancet 102 in Figures 6 and 7 has a tip) with a protective element (sleeve 104) comprising a sterilizing, microbicidal, inactivating, disinfecting, bacterialcidal or fungicidal material for cleaning or protecting the lancet tip (see Heller [0041] and [0042]).

Both Fritz and Heller teach lancet devices. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify protective element in the system taught by Fritz by incorporating the materials taught by Heller in order to prevent the contamination of the lancet tips since many diabetic people use lancet tips multiple times to lower the cost of monitor their glycemia, see Heller [0003].

Regarding claim 14 Fritz discloses the blood withdrawal system of claim 1 as set forth above, wherein after a puncturing motion the lancet tip is driven into the protective element (see [0021]). Fritz fails to disclose a system wherein a lancet can be used repeatedly to collect multiple blood samples and can be driven into the lancet tip protective element between puncturing motions. Heller teaches a system wherein a lancet can be used repeatedly to collect multiple blood samples and can be driven into the lancet tip protective element between puncturing motions (see Heller Abstract and Figures 6 and 7).

Both Fritz and Heller teach a system of using lancets. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the system taught by Fritz to include reusable lancets comprising a sterilizing elastic material as taught by Heller in order to prevent the contamination of the lancet tips since many diabetic people use lancet tips multiple times to lower the cost of monitor their glycemia, see Heller [0003].

Regarding claim 15 Fritz discloses the blood withdrawal system of claim 1 as set forth above, further comprising operating elements (the transport unity can be driven and controlled manually which allows the user to select which lancet is used, see [0035]) the user can use to set whether a new lancet from the lancet storage container or a lancet from the parking position in the lancet tip protective element that was used previously for taking a blood sample. Fritz fails to disclose a system wherein a lancet that was previously used to take blood is used for the subsequent blood taking process.

Heller teaches a lancet system wherein a lancet that was previously used for taking a blood sample is sterilized after used and can be safely used for the subsequent blood taking process (see Heller Abstract).

Both Fritz and Heller teach lancet devices it would have been obvious to a person of ordinary skill at the time of the invention to modify protective element in the system taught by Fritz by incorporating the sterilizing of lancets after use and using the same lancet for a subsequent blood taking process as taught by Heller in order to allow diabetic people to reuse lancet tips multiple times to lower the cost to monitor their glycemia, while preventing the contamination of the lancet tips, see Heller [0003].

Regarding claim 28 Fritz discloses the method of claims 18 as set forth above. Fritz fails to disclose the method wherein a lancet is used repeatedly to take a multiple blood samples and is driven into the lancet tip protective element between the puncturing motions. Heller teaches a method wherein a lancet is repeatedly used to take multiple blood samples and is driven into a sterilizing protective element between puncturing motions (see Heller Abstract and Figures 6 and 7).

Both Fritz and Heller teach methods of using lancets. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method as taught by Fritz to include reusable lancets comprising a sterilizing elastic material as taught by Heller in order to prevent the contamination of the lancet tips since many diabetic people use lancet tips multiple times to lower the cost of monitor their glycemia, see Heller [0003].

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fritz in view of Roe et al. (US 2002/0188224).

Fritz discloses the blood withdrawal system of claim 1 as set forth above, but fails to disclose the device further comprising a test element cartridge. Roe teaches a blood system comprising a test element cartridge (a cassette containing test media, see Abstract).

Both Fritz and Roe teach blood systems. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the system taught by Fritz to include a test element cartridge as taught by Roe in order to collect a series of bodily fluid samples without requiring disposal of the test media.

13. Claims 12 and 17 are rejected under U.S.C. 103(a) as being unpatentable over Fritz in view of Simons (US 6,071,294).

Regarding claim 12, Fritz disclose the blood system of claim 9 as set forth above. Fritz fails to disclose the device wherein the elastic material comprises a cover made of an absorbent material. Simons teaches a lancing device comprising a protective element (casing 222, see Figures 3A-3D) which comprises a cover (an absorbent material 218 around the aperture, see Column 10, Lines 1-15) made of an absorbent material.

Both Fritz and Simons teach lancet devices. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify protective element in the

system taught by Fritz by including a absorbent material cover as taught by Simons in order to soak up blood after lancing, see Simons Column 9, Lines 55-60.

Regarding Claim 17, Fritz discloses the blood withdrawal system according to claim 1. Fritz fails to disclose an analysis device. Simons teaches an analysis device for analyzing blood comprising a cartridge and several analysis methods incorporated with a lancet cartridge, see Column 7, Lines 60-67 and Column 8, Lines 1-12.

Both Fritz and Simons teach lancet devices. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify protective element in the system taught by Fritz by including an analysis device as taught by Simons in order to analyze glucose and other blood qualities, see Simons Column 8 Lines 1-12.

14. Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritz.

Regarding claim 21 Fritz discloses the method of claim 18 as set forth above. Fritz fails to disclose the method further comprising driving the lancet tip protective element onto the lancet tip, resulting in the lancet protective element surrounding the lancet tip. However, Fritz does disclose the method further comprising driving the lancet tip into the protective element, resulting in the lancet protective element surrounding the lancet tip. Both methods result in the same resulting structure. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify the method taught by Fritz by driving the protective element relative to the lancet

tip in order to result in a structure wherein the protective element surrounds the lancet tip.

Regarding claim 26, Fritz discloses the method of claim 25 as set forth above. Fritz fails to disclose a method further comprising inserting the used lancet, into the lancet tip protective element before transporting it back to the lancet storage container and placing it in the parking position. Fritz does disclose the method further comprising inserting the used lancet into the lancet tip protective element and transporting it back to the storage container and placing it in the parking position simultaneously, see [0021]. Therefore, Fritz discloses a method for accomplishing the same end result, the lancet tip enclosed by the protective element in the parking position, in one step what the applicants invention does in multiple. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify the method disclosed by Fritz by separating the single step into individual motions.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Stout whose telephone number is 571-270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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